

REMARKS

Objections to the Claims

The Examiner's objections to the claims' allegedly reciting an improper Markush group has been addressed by the amendments to the claims, and in particular the amendments to claim 23. Claim 23 as amended does not recite a Markush group and refers to "a method for the treatment of circadian rhythm disorders which comprises administration of an effective amount of a compound which modulates the activity of a VR2 polypeptide to a patient in need of such treatment." Withdrawal of the objections to the claims is therefore respectfully requested.

Objections to the Drawings

The Examiner's objections to the drawings have been addressed by amending the three sheets comprising FIGURE 1. The three FIGURE 1 sheets (i.e., sheets 1/7, 2/7 and 3/7) are now labeled FIGURE 1A, FIGURE 1B AND FIGURE 1C, respectively. Corresponding amendments have been made to the "Brief Description of the Drawings" section of the specification. Withdrawal of the objections to the drawings is therefore respectfully requested.

Claim Rejections – 35 USC §112

Claims 23, 29-35 and 43 (all claims now pending) stand rejected as allegedly failing to comply with the written description and enablement requirements. Applicants respectfully traverse.

The present invention lies in the discovery that VR2 modulators can be employed in a method of treating sleep-related conditions and disorders. The present invention is *not* the provision of specific VR2 modulators, and limiting the invention to the use of specific VR2 modulators would therefore inappropriately limit the scope of the claimed invention.

The present claims are supported by text at pages 24-26 of the specification, wherein it is revealed that VR2 polypeptide is expressed "*abundantly and discreetly*" in the primate brain, with "*highly intense*" concentrations observed at the suprachiasmatic nucleus (SCN) region of the brain. The SCN region is known in the art to be closely associated with sleep-related functions. Thus, one skilled in the art would, upon learning of the inventive leap described in the instant application, reasonably believe that VR2 modulators can be employed to treat sleep disorders. Use of specific compounds, dosages, route of administration and other

parameters would easily be determinable by those skilled in the art with routine experimentation and optimization.

The Examiner points out (without support) that certain mammalian cells which express VR2 are known to express many other proteins, and contends that a skilled artisan would therefore not believe that VR2 proteins on such cells would necessarily regulate sleep-related conditions and disorders. This contention is incorrect because it ignores the fact that VR2 is not merely expressed in the SCN, it is rather found to be present in *extremely high concentrations*. Coupled with knowledge in the art associating SCN with sleep functions, such a highly concentrated presence of VR2 expression would indeed lead a skilled artisan to conclude that VR2 modulators can be employed to treat sleep disorders.

The case law cited by the Examiner is simply not on point. In *Regents of the University of California v. Eli Lilly*, the Federal Circuit discussed the written description requirement as applied to claims for plasmids and microorganisms themselves, *not to methods of using such plasmids and microorganisms*. *Eli Lilly* is silent as to the written description required to support a method of use claim because method of use claims were not an issue in the Federal Circuit's evaluation of the '525 patent. *Eli Lilly* therefore cannot be relevant to the evaluation of the method of use claims in the referenced patent application.

Citation of *Ex parte Novitsky* is similarly misplaced because this case relates to inherent anticipation pursuant to §102, not to any §112 issue. The Examiner's point seems to be that he cannot determine if inherent anticipation applies because he does not have a compound to search. However, the Examiner might more appropriately search for an association between VR2 modulators generally and sleep-related conditions or disorders. It seems that no such association has been found by the Examiner.

Further, the *Colianni* case described a patent specification requiring the use of a "sufficient" amount of ultrasonic energy to fuse bones. This case is anything but "directly analogous" to the instant invention. *Colianni* deals with a wholly unrelated field of art, and centers on the adequacy of the term "sufficient" in describing the quantum of energy required to practice the invention. In *Colianni* the "sufficient" amount of energy is crucial to the invention and must be known with particularity. In contrast to *Colianni*, the methods claimed in the instant invention relate to *any* VR2 modulator and thus cannot be limited to particular VR2 modulators.

Finally, *Gentech v. Novo Nordisk* is cited for the proposition that an invention is to be disclosed such that its practice does not require an undue amount of experimentation. While the proposition is correct, it does not apply here, where determining a particular VR2

modulator to use with the claimed invention is well within the capabilities of the skilled artisan with only routine experimentation.

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In view of the amendments and remarks presented above, Applicants respectfully request that any objections and rejections of claims be withdrawn and a Notice of Allowance

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By: A. Reynolds Date: 9/22/06

Amendment to the Drawings

Kindly amend the drawing as follows:

Drawing sheet 1/7: Please amend "FIGURE 1" to read "FIGURE 1A".

Drawing sheet 2/7: Please add "FIGURE 1B" to the top of the page.

Drawing sheet 3/7: Please add "FIGURE 1C" to the top of the page.

For the convenience of the Examiner, amended drawing sheets 1/7, 2/7 and 3/7, reflecting the amendments to the drawings detailed above, are attached hereto.